

REMARKS

Claims 1-7, 9-12, 14, 21, and 22 are pending in the application with claims 1, 2, 4, 6, 7, 10, and 12 amended and new claims 21 and 22 added herein.

Claims 1-7, 9-12 and 14 stand rejected under 35 U.S.C. 112, as failing to comply with the written description requirement regarding the term “intermeshing loops.” Without admitting to the propriety of the rejection, claims 1 and 10 are amended herein to remove the allegedly offending subject matter to new claims 21 and 22.

Claims 1-7 and 9 stand rejected under 35 U.S.C. 112, as being indefinite. The phrase “the or each” in claims 1, 10, and 12 is amended herein accordingly. Claim 2 is amended herein to specify that the valve further includes a peripheral stent that provides a supporting wall, as described at least by page 2, lines 4-5 and page 4, lines 26-35 (also see Figs. 5a, b, and c). Claim 6 is amended herein to delete the allegedly offending subject matter. Applicant requests withdrawal of the rejections.

Claims 4 and 7 are amended herein to specify that the valve “further includes” a peripheral stent. Page 2 of the Office Action states that “the preamble is directed to the valve and the claims attempt to add a further element, the stent.” As supported at least by page 2, line 15, page 4, lines 5-16, page 4, lines 26-27, and page 5, lines 5-6 of the original specification, “a valve” can be stented or stentless. No indefiniteness arises by claiming that the valve “further includes a peripheral stent.” Those of ordinary skill interpreting the claims in light of the specification, as is required, would

discern the scope of claims 4 and 7 as being clear. Consequently, such claims are definite and Applicant requests withdrawal of the rejections.

Claims 1-7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiMatteo (US Patent No. 7,267,686) in view of Zilla (US Pub. No. 2005/0070995). Claims 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiMatteo in view of Zilla and Gabbay (US Pat. No. 6,869,444). Applicant requests reconsideration.

Amended claim 1 sets forth a prosthetic valve in the form of a flap valve that includes at least one flap being made entirely of a flexible openwork structure of a medically acceptable metal. The flexible openwork structure is selected from the group consisting of knitted wire and chain mail. Page 3 of the Office Action alleges that DiMatteo discloses every limitation of claim 1 except for the knitted wire and relies on Zilla to remedy the deficiency. Applicant traverses.

As stated in column 7, lines 34 et seq., the DiMatteo valve has several valve leaves 40 that include a valve leaf frame 52 defining a leaf frame aperture 62 sealed by a valve leaf cover 80. As stated in column 10, lines 21-49, leaf cover 80 is sufficiently thin and pliable so as to permit radially-collapsing the valve for delivery by catheter to a location within a body lumen. Leaf cover 80 may be a fluid-impermeable, biocompatible, non-thrombogenic material positioned on leaf frame 52 and other components of a trellis 24 so as to seal the leaf frame aperture 62. Leaf cover 80 seals leaf frame aperture 62 at least between component legs 54 and 56 of leaf frame 52 and hinge line 22. The material of leaf cover 80 may be Polyethylene (PE), Pellethane,

Urethane, bovine pericardial tissue, a surgically-useful textile (such as Dacron, Polyethylene terephthalate (PET), silk, Rayon, or the like), or a surgically-useful polymeric material (such as polytetrafluoroethylene (PTFE)).

It is readily apparent from columns 7-10 and corresponding Figs. 1-5 of DiMatteo that valve 10 includes a trellis 24 that has an open construction. Leaf cover 80 is secured over and moves with leaf frame 52, which forms a part of trellis 24. In all DiMatteo embodiments, leaf frame 52 and cover 80 together form valve leaf 40. DiMatteo fails to disclose any valve flaps made entirely of cover 80. DiMatteo in view of Zilla thus fails to suggest at least one flap made entirely of a flexible openwork structure of knitted wire or chainmail, as set forth in claim 1.

Also, page 3 of the Office Action alleges it would be obvious to modify DiMatteo by replacing cover 80 with knitted shape memory materials 165 of the tubular support for a venous graft in Zilla. As stated in paragraph 11 of Zilla, the tubular support may exhibit sufficient flexibility and resilience to provide the venous graft with compliance properties mimicking the compliance properties of an artery. Although flexibility is also a consideration for the knitted wire and chain mail of the prosthetic valve in claim 1, as discussed at least on page 3 of the original specification, Applicant asserts that the Office's modification frustrates the intended purpose of DiMatteo.

The mere fact that the prior art can be modified does not make the modification obvious "unless the prior art suggested the desirability of the modification." In re Gordon, 733 F.2d 900, (Fed. Cir. 1984). Accordingly, if a proposed modification of the prior art would render the prior art device or

process “inoperable for its intended purpose” or change the principle of operation of the prior art invention being modified, then no suggestion or motivation exists to make the proposed modification. Id.; In re Ratti, 270 F.2d 810, 813 (CCPA 1959); MPEP § 2143.01(V) (2007).

In paragraphs 53 and 55 and elsewhere throughout Zilla, knitted shape memory materials 165 containing metal wires provide an arterial reinforcement tubular support 77 designed for placement around a portion of a vein to produce an arterial graft. However, Zilla fails to disclose and the Office Action fails to allege that Zilla discloses the resulting wire mesh as possessing the properties required by DiMatteo for cover 80. That is, as stated in column 7, lines 34 et seq. of DiMatteo, valve leaf 40 includes valve leaf frame 52 defining leaf frame aperture 62 that is sealed by valve leaf cover 80. Leaf cover 80 is fluid-impermeable and is positioned on leaf frame 52 and other components of a trellis 24 so as to seal the leaf frame aperture 62. Leaf cover 80 seals leaf frame aperture 62 at least between component legs 54 and 56 of leaf frame 52 and hinge line 22.

The Office Action fails to provide substantial evidence that Zilla discloses knitted shape memory materials 165 as being suitable to satisfy the intended purpose in DiMatteo of valve leaf cover 80 sealing leaf frame aperture 62 as a fluid-impermeable material. Under the Administrative Procedure Act (APA) applicable to the Office’s allegation, the standard of review applied to findings of fact is the “substantial evidence” standard. See, In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). See also MPEP § 2144.03 (2007). Essentially, the Office’s allegation

appears to assume it is well-known that Zilla's knitted shape memory materials 165 would seal DiMatteo's leaf frame aperture 62. Patentee asserts this fact is not well known and traverses the allegation. It is not permissible for the Office to base rejections on unsupported assumptions.

Applicant asserts that the Office's proposed modification would frustrate the intended purpose of DiMatteo since it is readily apparent from Zilla's description of knitted shape memory materials 165 in the form of a wire mesh that the mesh would not be fluid impermeable. Consequently, no motivation may be considered to exist to make the Office's proposed modification of DiMatteo. Claim 1 is thus patentable at least for such additional reasons.

Applicant notes as a further point, that the use of a knitted structure in Zilla is for a quite radically different purpose than DiMatteo. In Zilla, the tubular structure formed by the knitted wire is used as an external support for a vein or artery. In Zilla, the structure undergoes no significant fatigue stresses since the cyclic pressure on the structure is minimal (i.e. it is exposed only to the variations in pressure caused by the beating of the heart). In contrast, in DiMatteo, the valves are subject to significant degrees of movement since, for the valve to function, the flaps need to move by a relatively large amount. Thus, a structure which is suitable for use in Zilla would not automatically be assumed by those of ordinary skill to be suitable for use as a valve flap. The two applications are in fact very different and require different properties. The Office Action fails to provide substantial

evidence that those of ordinary skill would deem the Zilla wire mesh as suitable for use in the DiMatteo valve.

Applicant notes as a still further point, that even if the disclosure of Zilla is applied to the disclosure of DiMatteo as set out in the Office Action, then the resulting structure would be a valve leaf frame as disclosed in DiMatteo covered by a metal mesh of the type disclosed in Zilla. Such a device still fails to disclose a valve flap made entirely of a flexible openwork metal structure, as set forth in amended claim 1. At least for such further and still further reasons, claim 1 is patentable.

Claims 2-7, 9, and 21 depend from claim 1 and are patentable at least for such reason as well as for the additional limitations of such claims not disclosed or suggested.

Amended claim 10 sets forth a method that includes, among other features, providing in a living subject a prosthetic valve in the form of a flap valve that includes at least one flap arranged to allow movement of liquid through the prosthetic valve only in one direction. The at least one flap is made entirely of a flexible openwork structure of a medically acceptable metal selected from the group consisting of knitted wire and chain mail. As may be appreciated from the discussion above regarding the deficiencies of DiMatteo in view of Zilla, the cited combination fails to suggest a valve with at least one flap made entirely of a flexible knitted wire or chain mail. At least for such reason, amended claim 10 is patentable. Claims 11, 14, and 22 depend from claim 10 and are patentable at least for such reason as well as for the additional limitations of such claims not disclosed or suggested.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiMatteo in view of Gabbay and Yang (US Pub. No. 2002/0138138).

Applicant requests reconsideration.

Amended claim 12 depends ultimately from claim 10 and sets forth that the method further includes coating the at least one flap of the heart valve with an inert degradable sealing material when the valve is initially fitted. The material reducing leakage through the flexible openwork structure until the living subject develops a coating by endothelialization.

At least page 5, lines 30-33 of the original specification define the "degradable" characteristic of the sealing material set forth in amended claim 12 and its advantages. The lubricious material described in paragraph 59 of Yang, especially the example of PTFE, fails to meet the definition in the present specification of a degradable sealing material. The Office Action does not provide evidence that it would "degrade" within the meaning of claim 12. Page 4 of the Office Action merely assumes that the lubricious material of Yang, such as PTFE, constitutes degradable material. Consequently, the rejection lacks support based on substantial evidence, as is required for a proper rejection, and should be withdrawn.

Under the Administrative Procedure Act (APA) applicable to the Office's allegation of degradability, the standard of review applied to findings of fact is the "substantial evidence" standard. See, In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). See also MPEP § 2144.03 (2007). Essentially, the Office's allegation appears to assume it is well-known that PTFE may be degradable. Applicant asserts this fact is not well

known and traverses the allegation. It is not permissible for the Office to base rejections on unsupported assumptions.

Applicant asserts that PTFE is well-known for resisting all forms of degradation. It is well-known as a very tough coating that those of ordinary skill would expect to remain in situ as reliable lubrication for the life of the valve. Those of ordinary skill who wanted a degradable coating would not select PTFE as a coating material. At least for such reasons, Applicant asserts that claim 12 is patentable.

Applicant notes that new claims 21 and 22 depend from respective claims 1 and 10 and specify that the knitted wire has intermeshing loops. The subject matter of claims 21 and 22 was previously rejected as allegedly failing to comply with the written description requirement. Applicant refers the Office to the specification for interpretation of the term "knitted wire." Specifically, page 3, lines 15-23 refer to Figures 7a-d and state that the openwork structure may be made from wire using a knitting type of process. Alternatively, a weaving type of process may be used. Knitted wire is shown in Figure 7a while woven wire is shown in Figure 7b. Woven flaps are described as providing a relatively stiff structure while knitted flaps are more flexible.

Consequently, the present specification expressly distinguishes knitted wire from woven wire, both with respect to appearance as well as stiffness. Figure 7a shows the intermeshing loops characteristic of a knitted material while Figure 7b contrasts such loops with the warp and weft threads running at right angles to each other characteristic of a woven material.

Previously, the Office relied on Webster's Revised Unabridged Dictionary available from Dictionary.com and referred to "knit" as "to form a fabric by interlacing yarn or thread; to weave by making knots or loops." The same reference relied on by the Office further refers to "knit" as "to form, as a textile fabric, by the interlacing of yarn or thread in a series of connected loops, by means of needles, either by hand or by machinery; as, to knit stockings." Thus, Webster's refers to "knit" in one generic sense as forming fabric by interlacing yarn or thread. However, it is apparent from the present specification that "knitted wire" in claims 21 and 22 refers to a more narrow sense of material including the intermeshing loops of Figure 7a and possessing a flexibility greater than woven material of the type shown in Figure 7b. "Knitted wire" in claims 21 and 22 thus corresponds with the more narrow definition for "knit" in Webster's.

Applicant further refers the Office to the definitions provided in the Larousse Technical Dictionary cited in a previously filed Information Disclosure Statement. Larousse defines "knitting" as "the process of making a fabric from yarn by the formation of intermeshing loops" and defines "weaving" as "the interlacing of warp and weft threads running at right angles to each other to form a fabric." Notably, it is relevant to consider that in a weave there are two sets of threads (i.e. warp and weft), which extend in different directions whereas, in a knit, thread is interlaced with itself. The present specification is consistent with the definitions presented in Larousse.

Consequently, the present specification fails to expressly state the terms "intermeshing loops." However, Applicant asserts that claims 21 and

22 possess a proper written description in keeping with 35 USC 112, first paragraph when appropriately interpreted in light of the specification and in keeping with the ordinary meaning of “knitted” or “knitting”.

Applicant herein establishes adequate reasons supporting patentability of claims 1-7, 9-12, 14, 21, and 22 and requests allowance of all pending claims in the next Office Action.

Respectfully submitted,

Dated: September 8, 2009

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